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ATTORNEY DOCKET NO. CONFIRMATION NO. FIRST NAMED INVENTOR APPLICATION NO. FILING DATE 01/06/2000 Patricia D. Wilson A3275970165.0555 2081 09/478,737 EXAMINER 03/09/2004 21003 7590 BAKER & BOTTS MURPHY, JOSEPH F 30 ROCKEFELLER PLAZA ART UNIT PAPER NUMBER NEW YORK, NY 10112 1646

Please find below and/or attached an Office communication concerning this application or proceeding.

	Application No.	Applicant(s)
Office Action Summary	09/478,737	WILSON ET AL.
	Examiner	Art Unit
	Joseph F Murphy	1646
The MAILING DATE of this communication appears on the cover sheet with the correspondence address Period for Reply		
A SHORTENED STATUTORY PERIOD FOR REPL THE MAILING DATE OF THIS COMMUNICATION.  - Extensions of time may be available under the provisions of 37 CFR 1.1 after SIX (6) MONTHS from the mailing date of this communication.  - If the period for reply specified above is less than thirty (30) days, a repl If NO period for reply is specified above, the maximum statutory period Failure to reply within the set or extended period for reply will, by statute Any reply received by the Office later than three months after the mailing earned patent term adjustment. See 37 CFR 1.704(b).	136(a). In no event, however, may a reply be tin by within the statutory minimum of thirty (30) day will apply and will expire SIX (6) MONTHS from the, cause the application to become ABANDONE	nely filed  rs will be considered timely.  the mailing date of this communication.  D (35 U.S.C. § 133).
Status		
1) Responsive to communication(s) filed on 20 January 2004.		
· ` ` ` ·	This action is <b>FINAL</b> . 2b)⊠ This action is non-final.	
3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is		
closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11, 453 O.G. 213.		
Disposition of Claims		
4) Claim(s) 21-37 is/are pending in the applicatio 4a) Of the above claim(s) is/are withdray 5) Claim(s) 24-29, 31-36 is/are allowed. 6) Claim(s) 21-23 is/are rejected. 7) Claim(s) 30 and 37 is/are objected to. 8) Claim(s) are subject to restriction and/or Application Papers  9) The specification is objected to by the Examine 10) The drawing(s) filed on is/are: a) accomplication and request that any objection to the Replacement drawing sheet(s) including the correct 11) The oath or declaration is objected to by the Examine 11.	wn from consideration.  or election requirement.  er. epted or b) objected to by the I drawing(s) be held in abeyance. See tion is required if the drawing(s) is objected.	e 37 CFR 1.85(a). jected to. See 37 CFR 1.121(d).
Priority under 35 U.S.C. § 119		
12) Acknowledgment is made of a claim for foreign a) All b) Some * c) None of:  1. Certified copies of the priority document 2. Certified copies of the priority document 3. Copies of the certified copies of the priority application from the International Bureau * See the attached detailed Office action for a list	s have been received. s have been received in Applicati rity documents have been receive u (PCT Rule 17.2(a)).	on No ed in this National Stage
Attachment(s)		
1) Notice of References Cited (PTO-892) 2) Notice of Draftsperson's Patent Drawing Review (PTO-948) 3) Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date	4) Interview Summary Paper No(s)/Mail Da 5) Notice of Informal P 6) Other:	

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## **DETAILED ACTION**

## Request for Continued Examination

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 1/20/2004 has been entered.

## Formal Matters

Claims 21-37 are pending and under consideration.

# Specification

The abstract of the disclosure is objected to because it is entitled "Abstract of the Invention". Pursuant to 37 CFR 1.72 a brief abstract of the technical disclosure in the specification must commence on a separate sheet, preferably following the claims, under the heading "Abstract" or "Abstract of the Disclosure". Correction is required. See MPEP § 608.01(b).

## Claim Objections

Claims 30 and 37 stand objected to because of the following informalities: They are dependent on cancelled claims. Appropriate correction is required.

## Response to Amendment

The rejection of claim 26 under 35 USC § 112 second paragraph has been obviated by Applicant's amendment and is thus withdrawn.

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# Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 21-23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wilson et al. (1996) in view of Van Adelsberg (1999), for reasons of record set forth in the Office Action of 2/11/2003. The references were cited and provided in that Office Action.

Wilson teaches the correlation between PKD-1 content and degree of adherence to type I collagen. Van Adelsberg teaches peptide inhibitors derived from the PKD repeats of polycystin-1 (page 301, Figure 1). It would have been obvious to one of skill in the art at the time the invention was made to measure adherence of polycystin-1 expressing cells to collagen type-1 in the presence of the inhibitory peptides derived from the PKD repeats of polycystin-1 as taught by Van Adlesberg, with a reasonable expectation of success. One of skill in the art at the time the invention was made would have been motivated to make this modification to determine if type I collagen is a ligand for polycystin-1.

Claims 21 and 23 of the instant application do not contain a limitation whereby the polycystin-1 used in the assay is a mutant polycystin-1, while claim 22 is drawn to screening methods using mutant polycystin-1. The Van Adelsberg reference teaches methods of measuring the effects of peptides derived from PKD-1 extracellular domain on polycystin-1 function, and screening those peptides for effect on ureteric bud branching morphogenesis. The Van Adelsberg reference further teaches that mutations in the PKD1 gene are responsible for about

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85% of autosomal dominant polycystic kidney disease (Van Adelsberg page 299, column 1, first paragraph). The Wilson reference also teaches that mutations in the PKD-1 gene causes autosomal dominant polycystic kidney disease, and further teaches assays to measure adherence of cells comprising PKD-1 to collagen type I, including asays using ADPKD epithelia which comprise mutant PKD-1. Given the screening method of Van Adelsberg, and the teaching of Wilson on measuring the adherence of PKD-1, including mutant PKD-1, to type I collagen, the combination of Van Adelsberg and Wilson references render it obvious to practice a method of identifying compounds which modulate polycystin-1, and mutant polycystin-1, mediated increase in adherence to Type I collagen.

## Conclusion

Claims 24, 25, 26, 27, 28, 29, 31, 32, 33, 34, 35, 36 are allowable.

Claims 21-23 are rejected.

Claims 30 and 37 are objected to.

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# Advisory Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Joseph Murphy whose telephone number is (571) 272-0877. The examiner can normally be reached Monday through Friday from 7:30 am to 5:00 pm. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler can be reached on (571) 272-0871.

The fax number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Joseph F. Murphy, Ph. D.

Patent Examiner Art Unit 1646

February 24, 2004